REMARKS

Careful consideration has been given to the Official Action of April 18, 2005 and reconsideration of the application as amended is respectfully requested.

Elections/Restrictions

Figs. 30 and 31 have been elected as Species X.

As previously submitted, claims 57-60 are considered linking claims of the apparatus of invention I and the method of invention II. The Examiner has considered that since claim 57 is only dependent from claim 37 and invention II (method) does not require all the limitations of the apparatus as claimed in claim 37, claim 57 does not qualify as a linking claim. In order to overcome this objection by the Examiner, claim 57 has been rewritten in independent form and incorporates all of the limitations from claim 37.

Since claim 57 is now deemed to be a proper linking claim (by the definition of the Examiner) it is entitled to examination in this application. The fact that it is limited to the species of figs. 30 and 31 does not affect its status in this regard and indeed the fact that there are claims which are directed to other species (either apparatus or method) is irrelevant to the question of whether claim 57 is a valid linking claim. Contrary to the apparent conclusion of the Examiner, a linking claim can indeed be directed to a particular species.

The Examiner considers that claims 3, 4, 6-9, 12, 14 and 17 do not read on the elected species because "the Species X does not have second bend portion integrally formed with the first portion by a bend (one bend) and the first portion further has two spaced wires as required by [these] claims". The contention of the Examiner is respectfully traversed as the

recitation of "a bend" in claim 1 does not foreclose the inclusion of more than one bend. The claim is cast in "comprising" form and therefore is open ended thus admitting of more than one bend. The claim is not limited to "one bend" as alleged by the Examiner, see Gillette Co. v. Energizer Holdings Inc. 74 USPQ 2nd 1586. Nevertheless, in order to clearly admit the possibility of one or more bends, the language of claim 1 has been amended to call for "at least one bend." Thereby claims 3, 4, 6-9, 14 and 17 no longer suffer the alleged disability as stated by the Examiner and are entitled to examination as claims directed to the elected Species of Figs. 30 and 31.

The Examiner's comments regarding claims 5 and 10 are well taken and these claims are excluded from the claims which read on the elected Species.

The Examiner contends that figs. 30 and 31 do not require the application of a pulling force as set forth in claims 57-60. In actuality, the pulling force can be applied by hand as explained in the specification (page 8, lines 9-12). The utilization of the tensioning device shown in other figures is not mandatory in figs. 30 and 31 to achieve the tension in the implant. However, the bone screw(s) 16 secure the second portion to the bone while the implant is in tension.

Claim Rejection-35 U.S.C. 112

The Examiner has raised objection to claim 56 at line 2 for lacking antecedent support and the claim has been amended to overcome the objection. Also the typographical error in claim 56 has been corrected.

Claim Additions

Claims 61-64 have been added and are dependent from a respective independent claim 1 or 37. These claims read on the elected species of Figs. 30 and 31.

Claim Rejections-35 U.S.C. 102

The Examiner has rejected claims 1,37-39, 42, 48 , 50 and 56 under 35 U.S.C. 102 as being anticipated by Sagawa.

In order to clearly distinguish the claimed invention from Sagawa amendatory action has been taken in the claims.

Before discussing the amendatory action, it is respectfully submitted that the present invention is entirely distinct from Sagawa both structurally and functionally. In this regard, the invention is directed to an implant device which can be implanted in a fractured bone for applying compression across the fracture site. Sagawa is directed to a cerebral aneurysm clip used for clamping an intercerebral blood vessel during a surgical operation. These are completely dissimilar uses and require dissimilar devices.

The fracture fixation implant of the invention has a first portion or leg which is constructed and arranged to be implanted within a bone across a fracture site in the bone. Sagawa shows no such implanting of any part of its clip within a bone across a fracture site and no construction or arrangement of any part for implanting in a bone. Sagawa shows a pair of arms 11 which confront each other and can be moved apart to serve as blood clamping

blades. These arms are not constructed and arranged to be implanted into the bone across a fracture site as claimed. At the end of the clamping arms 11, engagement portions 12 are formed which are made of a resilient wire and these extend to bends 13a connected together by a portion13b. The resilient portion 13, made up of bends 13a and connecting portion 13b, acts to exert a resilient force onto the engagement portion 12 so as to urge the confronting surfaces of the clamping arms 11 against each other. A U-shaped wire element 18 is provided on the clip and includes a transverse section 18a which passes through holes 17 in the arms 11. The wire element 18 does not serve a spring function but is provided only for the transverse section 18a to serve as a blocking means for the blood vessel and prevent the clip 10 from advancing further (column 5, lines 1-7). Basically, Sagawa discloses a clip having a pair of separable arms 11 connected by a resilient portion 13 which allows the arms to be opened and closed to achieve a clamping function on a blood vessel. This is completely distinguishable from the implant of the invention which requires a first leg to be implanted in the bone and a second leg connected by a bend portion to extend backwardly in opposite direction from the first leg in juxtaposition therewith to pass on a superficial surface of the bone. By exerting a pulling force on the second leg, the implant will be subjected to tension and this tension in the implant is maintained by the fixation means including the bone screw secured in the bone. In this way, the tension in the implant produces compression across the fracture and this compression is preserved when the implant is secured to the bone and assist in the fixation and healing of the bone. Furthermore, not only must the first leg be constructed and arranged to be impacted into the bone, it needs to be of a size and length to remain in the bone and resist the pulling force applied to the second portion lying outside the bone. Notably, Medoff secures the device to the upper surface of the bone whereas the

fixation device (bone screw and washer) secure the reverse-bend leg to the bone at the lower surface thereof. Hence one leg is embedded in the bone and the other leg extends backwardly from the reverse bend and is secured, with the device under tension, to the outer lower surface of the bone.

Claim 1 clearly distinguishes over Sagawa by calling for the first leg to be constructed and arranged to be implanted into the bone and by the fixation element which is secured to the bone and maintains the tension developed in the implant. While Sagawa shows a wire having bends and arms these do not structurally meet the terms of claim 1 and in fact function in an entirely different manner. In its simplest aspect Sagawa shows a clamp in which the two legs 11 are elastically biased together by the portion 13 with the bends. There is no way that Sagawa could remotely be considered to be modified to carry out the function ascribed to the implant of the invention serving for applying compression across the fracture site and maintaining this compression.

Claim Rejections-35 U.S.C. §103

The Examiner has rejected claims 1, 37-39, 40, 42, and 48 under 35 U.S.C. as being unpatentable over Lee in view of Medoff.

Lee discloses a skull fixation device in the form of a clamp which is intended to connect the rim of a hole in the skull with a cut piece of skull intended to fill the hole. The clip is constructed with an upper portion10 and a lower portion 30 which serve to respectively clamp edges of the hole and of the cut skull. There is no impaction of any part into a bone and there is no tension developed and maintained in the clip to apply compression across a fracture site as in the present invention. Nor is there a fixation means to secure the element to

the bone to maintain the tension in the implant and continue to apply compression across the fracture site. The construction and function of the clip in Lee bears no relation whatsoever to the implant of the claimed invention. Indeed, there is no way in which one skilled in the art could be directed by Lee to utilize the clip to arrive at the claimed invention. The mere existence of a bent wire as in Lee affords no teaching upon which to produce juxtaposed legs one of which is implanted into the bone so that by applying a pulling force to the other, backwardly and juxtaposed, leg a tension can be developed to apply compression across a fracture site.

The Examiner cites Medoff for showing a washer and bone screw and proposes utilizing this in Lee. As correctly noted by the Examiner, the washer and bone screw of Medoff secure the apparatus to a stable bone. It is not seen how or where the bone screw and washer of Medoff could be employed in Lee to achieve a securing function. Furthermore, the purpose of the clips in Lee are specifically to avoid drilling a hole in the skull which could result in the prolongation of the surgical operation and the post-surgical healing process (column 1, lines 13-17).

As for Medoff, it is to be noted that there is no disclosure of producing tension in the implant nor of maintaining the tension to produce compression across the fracture. In fact, Medoff relies on a buttressing effect on the intraosseous surface to produce a clamping effect. The bone screw and washer only serve a securing function but not to preserve a tension developed in the implant to achieve compression across the fracture site. Notably, Medoff secures the device to the upper surface of the bone whereas the fixation device (bone screw and washer) secure the reverse-bend leg to the bone at the lower surface thereof. Hence one

leg is embedded in the bone and the other leg extends backwardly from the reverse bend and is secured, with the device under tension, to the outer lower surface of the bone.

Therefore, it is respectfully submitted that by combining Lee and Medoff one skilled in the art cannot arrive at the claimed invention without total reorganization of the references and exercising an inventive step. This is because neither Lee nor Medoff singly or in combination discloses or suggests the features described above and set forth in the claims.

In that regard, the examiner is cautioned that in assessing the patentability of a claim against a combination of prior art references, the analysis must be conducted without hindsight of the present invention, and must be based only on what one skilled in the art would be taught or what would be obvious from the respective disclosures at the priority date of the present application. It is well settled that the suggestion or motivation to make the combination or modification must be found in the prior art, and not in applicant's own disclosure. M.P.E.P. § 2143.

It is respectfully submitted that with this proper assessment of the patentability of the present invention under 35 U.S.C. 103(a), one is left with recognizing that a person skilled in the art would have to perform a non-obvious step to arrive at the invention as claimed in, for example, claims 1 and 37.

It is therefore respectfully submitted that the cited art fails to satisfy the anticipation requirement under 35 U.S.C. 102 or the obviousness requirements under 35 U.S.C. 103. In order to arrive at the invention as claimed in claims 1 and 37 and the claims dependent therefrom, one would have to disregard or distort the teachings in Sagawa and Lee in favor of the unrelated teaching in the invention. There is no suggestion to ignore the teachings in

Sagawa or Lee without using applicants' own disclosure as a template, and no such suggestion can be found in the references. "To establish prima facie case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art" MPEP § 2143.03. As explained above, the references do not show or suggest the limitations now present in the claims and there is no motivation or incentive in the references to do so. As held in Ex parte Clapp 227 USPQ 972 in order to conclude that the claimed invention is anticipated or directed to obvious subject matter, the references must either expressly or impliedly teach or suggest the claimed invention. This they cannot do for the reasons expressed above.

In view of the above action and comments, it is respectfully submitted that the claims as now amended are patentably distinct from the cited art and favorable reconsideration is earnestly solicited.

Respectfully submitted,

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